

REMARKS

Claims 22 – 52 are pending in this application, and claims 1 - 21 have been canceled without prejudice. New matter has not been introduced by the present amendment. Claims 22, 28 and 33 are independent claims directed to a coating. The new claims are supported by the original claims and recite further limitations with respect to the components of the coating; the modified starch, the secondary polymer and the plasticizer. Additionally, new claims 41 – 52 are supported by original claims 4 – 11 and 14 – 21.

Original claims 1 – 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oshlack et al., (U.S. Pat. No. 5,639,476). Applicants assert the present claims are patentable over the cited reference. There are no other rejections in the application.

Oshlack et al. is directed to a stable solid controlled release formulation coated with an aqueous dispersion of a hydrophobic acrylic polymer, particularly an aqueous dispersion of plasticized acrylic polymer. (See column 7, lines 35 – 38). The reference teaches that the acrylic polymer may be derived from acrylic acid or derivatives thereof. Acrylic acid derivatives include the esters of acrylic acid and methacrylic acid, and the alkyl esters of acrylic acid and methacrylic acid.

The reference further discloses that the hydrophobic acrylic polymer coating may include other components. These components may include:

- (1) Other monomers, such as styrene and its homologs, vinyl esters, such as vinyl acetate, and vinyl chloride, acrylamide, methacrylamide, hydroxy alkyl esters of acrylic acid and methacrylic acid and vinyl pyrrolidone (See column 7, lines 56 – 63 and column 9, lines 63 – 67).
- (2) One or more polymerizable permeability enhancing compounds, including at least one polymersizable quaternary ammonium compound. These compounds are strong bases, and particular examples of quaternary ammonium compounds are listed in column 8, lines 30 – 67 and column 9, lines 1 – 8 of the reference.
- (3) A long laundry list of pore forming polymers such as hydroxypropylmethylcellulose; cellulose ethers such as hydroxyalkylcelluloses

and carboxyalkylcelluloses; protein derived materials; polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, saccharides and polysaccharides, such as pullulan, dextran, sucrose, glucose, fructose, mannitol, lactose, sorbitol, alkali metal salts, polymers such as Carbowax®, starch, modified starch and starch derivatives, gums, ion-exchange resins, polycarbonates and others (See column 10, lines 45 – 67 and column 11, lines 1 – 41).

- (4) Plasticizing agents for the acrylic coating (See column 12, lines 29 – 60 and column 13, lines 1 – 25).

In a preferred embodiment, the coating of the reference is directed to copolymerizates of acrylic and methacrylic acid esters with a low content of quaternary ammonium groups and a further material selected from the group of polymerizable permeability enhancing agents, water-soluble acrylic polymers, pore-formers and mixtures thereof. The preferred permeability enhancing agent is a monoethylenically unsaturated quaternary ammonium compound capable of free-radical polymerization.

The coating claimed by the Applicants is not an aqueous dispersion of a hydrophobic acrylic polymer nor an aqueous dispersion of a plasticized acrylic polymer. Moreover, Applicants' claimed coating is not directed to an acrylic coating used in combination with a polymerizable permeability enhancing compound, including at least one polymersizable quaternary ammonium compound.

While the cited reference may include various components of the claimed coating, such as a plasticizing component or a modified starch, the reference as a whole does not teach or disclose the coating claimed by the Applicants. Applicants have claimed:

- (1) A coating which comprises a modified starch wherein the modification to the starch includes ethylation, acetylation, methylation, hydroxypropyl substitution, hydroxyethyl substitution, carboxymethyl substitution or hydroxypropyl methyl substitution; a plasticizer; and a modified cellulose as a secondary polymer.
- (2) A coating consisting essentially of a modified starch wherein the modification to the starch includes ethylation, acetylation, methylation,

hydroxypropyl substitution, hydroxyethyl substitution, carboxymethyl substitution or hydroxypropyl methyl substitution, and a plasticizer.

- (3) A coating which comprises a modified starch and a secondary polymer wherein the secondary polymer is selected from the group consisting of modified celluloses, polyvinyl alcohols, and polyvinyl pyrrolidones.

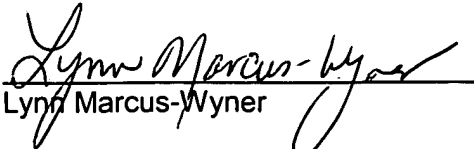
Applicants submit the cited reference neither discloses or provides any motivation to make the coating as claimed in the instant invention. It is a well-known tenet of patent law that for a reference to make a claimed invention obvious, the reference must provide one of ordinary skill in the art the motivation to make the modifications needed to arrive at the claimed invention. Moreover, beyond looking at the cited prior art to determine if it suggests doing what the inventor has done, one must also consider if the cited art provides the required expectation of success. (In re Dow Chemical 473 USPQ2d 1529 (Fed. Cir 1988). Both the suggestion and the expectation of success must be founded in the cited prior art and not in Applicants' disclosure. Applicants assert a *prima facie* case of obvious has not been made because both the suggestion of the claimed coating and the expectation of success are not found in the cited reference.

While it is true that the hydrophobic acrylic polymer coatings of the reference may be used to coat substrates such as tablets, beads, microspheres, seeds, pellets, and the like, the coating of the instant invention is different and non-obvious from the reference's disclosure, and therefore substrates including the claimed coating are also unobvious.

Applicants respectfully request that the rejection over Oshlack et al. be withdrawn. Pending claims 22 – 52 are in form for allowance, and allowance of the application is kindly solicited.

Respectfully submitted,

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Lynn Marcus-Wyner

Registration No. 34,869
Attorney for Applicants

Genencor International, Inc.
925 Page Mill Road
Palo Alto, CA 94304-1013
Tel: 650-846-7620
Fax: 650-845-6504